



UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

V.

ALAN MacKENZIE, et al

Defendants

01-CR-10350-DPW

**Government's Memorandum Regarding RTP as a Kickback  
Under Paragraph 55(b) of the Conspiracy Charged in Count I**

The government submits this memorandum to further illuminate why return to practice, when marketed as an inducement to obtain or keep Lupron business, constitutes a kickback violation, and is not protected conduct under either the affirmative defense of the statutory discount exception or the regulatory safe harbor.

**I. Marketing RTP Constitutes a Violation of the the Anti-Kickback Act.**

The Medicare Anti-Kickback statute provides that "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, covertly or overtly, in cash or in kind to induce such person. . . to purchase, lease, order . . . any good or service or item for which payment may be made in whole or in part under [Medicare] . . . shall be guilty of a felony . . ." 42 U.S.C. § 1320a-7b(b)(2). Every purchaser of Lupron was able to obtain a "list price" for the drug which was lower than average wholesale price (AWP), and the spread between list price and AWP was known to the government in various ways, and assumed by the Medicare reimbursement system. What was neither assumed nor known to the government was that TAP and these conspirators gave deep discounts to doctors off that list

price and *marketed* the ensuing spread between the doctor's deeply discounted cost and anticipated Medicare reimbursement as an inducement to obtain and keep Lupron business.

There is evidence of the following in this trial: (1) that deep discounts were given to doctors off list price, (2) that TAP *marketed* the ensuing spread to obtain and keep Lupron business (Elaine Morgan's audit reviews were explicit on how the information was marketed), and (3) that TAP increased the list price (and, as a result, the published AWP in the Red Book) to increase that spread when faced with financial competition from Zoladex (Durand testimony). Thus, TAP overtly offered remuneration (RTP), that was paid indirectly (through Medicare program funds) to obtain and keep Lupron business in violation of the Anti-Kickback Act.

The Court has asked what "duty to disclose" exists in connection with these deeply discounted prices, on the part of TAP or on the part of the doctor. That duty is derived from the statutory discount exception to the Medicare Anti-Kickback statute. That statutory exception provides "(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program *if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.*

42 U.S.C. § 1320a-7b(b)(3)(A). (emphasis added). Congress enacted the statutory discount exception in 1977 among a set of amendments to the Medicare Anti-Kickback Act that increased the penalty for a violation of the statute from a misdemeanor to a felony. In enacting these 1977 amendments, Congress sought to encourage medical providers to obtain common, every day discounts and price reductions where those benefits were properly disclosed and appropriately passed through to federal health care programs; Congress also sought to increase the

enforcement tools available to prevent widespread, abusive practices in the health care industry.<sup>1</sup>

In incorporating this exception to the general prohibition of the Anti-Kickback Act, Congress recognized the value of discounts, and the benefit that having providers purchasing at a discount could mean for the Medicare program. As noted by Judge Keeton:

[T]he discount exception makes good sense. The statute was passed to curtail fraud and abuse in Medicare and Medicaid reporting, in particular. It was passed to prevent health care service and good suppliers and providers from depriving the federal and state health care subsidy system of the benefits that a free market for health care services and goods can provide. By allowing for suppliers and providers of health care service and goods to compete with one another in limited forms, the statute strikes a balance: on the one hand, it provides for some of the benefits of a market economy by encouraging limited forms of price competition; on the other hand, it deters and *penalizes other types of conduct that would lower the cost of some health care services and goods for some suppliers and providers but would not pass on that lowered cost to the federal and state health systems or to its patients.*

United States v. Shaw, 106 F. Supp. 2d 103, 115 (D. Mass. 2000). Thus the statutory discount exception means that suppliers (such as TAP) and providers (such as physician customers of

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<sup>1</sup>In 1977, Congress perceived pervasive fraud and abuse in the health care industry with regard to the Medicare and Medicaid programs:

In recent years, numerous hearings, studies, and investigations undertaken by this committee and other committees of the Congress, the General Accounting Office, and other Federal and State agencies have demonstrated that there exist, to a disturbing degree, fraudulent and abusive practices associated with the provision of health services financed by the medicare and medicaid programs. . . [Fraud] cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program. It diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services. The wasting of program funds through fraud also further erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit and ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.

H.R. Rep. No. 393(II), 95<sup>th</sup> Cong., 2d Sess., *reprinted in* 1977 U.S. Cong. Code & Admin News 3039, 3046-47.

TAP) have a "duty to disclose" because they must "properly disclose" and "appropriately reflect" their discounts, to meet this exception to the prohibitions of the Anti-Kickback statute.

## II. Meeting the Statutory Discount Exception is an Affirmative Defense.

The statutory discount exception is an affirmative defense that the defendants had the burden to prove at trial.

It is a well-established rule of statutory construction that an exception set forth in a distinct clause or provision should be construed as an affirmative defense and not an essential element of the crime. United States v. Riviera, 183 F.3d 367, 370-71 (5<sup>th</sup> Cir. 1999); McKelvey v. United States, 260 U.S. 353, 357 (1922); "By repeated decisions it has come to be a settled rule in this jurisdiction that an indictment or other pleading founded on a general provision defining the elements of an offense . . . need not negative the matter of an exception made by a proviso or other distinct clause . . . and that it is incumbent on one who relies on such an exception to set it up and establish it."; United States v. Chodor, 479 F.2d 661, 663 (1<sup>st</sup> Cir.) (citing McKelvey), cert. denied, 414 U.S. 912 (1973); United States v. Ramzy, 446 F.2d 1184, 1186 (5<sup>th</sup> Cir.), cert. denied, 404 U.S. 992 (1971); United States v. Roy, 574 F.2d 386, 391 (7<sup>th</sup> Cir. 1978) ("An indictment founded on a general provision in a statute need not negative an exception made by a proviso or other distinct clause, whether in the same section or elsewhere."); Chin Gum v. United States, 149 F.2d 475, 479-80 (1<sup>st</sup> Cir. 1945).<sup>2</sup>

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<sup>2</sup>In United States v. Vuitch, 402 U.S. 62 (1971), the Supreme Court noted that where an exception was incorporated in the enacting clause of the statute, the burden was on the prosecution to plead and prove the defendant was not within the exception. *Id.* at 70. Here, the discount exception of the Medicare Anti-Kickback Act was not incorporated in the enacting clause of illegal remunerations set forth in 42 U.S.C. § 1320a-7b(b)(1) and (2), but was set forth as one of five separately enumerated exceptions, so the prosecution bears no such burden here.

In interpreting criminal statutes, courts routinely hold that separately cast exceptions are affirmative defenses. For example, in interpreting the federal machine gun statute, 18 U.S.C. § 922(o), the Fifth Circuit held that where the statute prohibited unlawful possession of a machine gun but contained an exception in a separate subsection for lawful possession prior to the statute's effective date, the exception was an affirmative defense. United States v. Gonzales, 121 F.3d 928, 936-37 (5<sup>th</sup> Cir. 1997), cert. denied, 118 S.Ct. 726 (1998); accord United States v. Just, 74 F.3d 902, 904 (8<sup>th</sup> Cir. 1996); see also United States v. Steele, 147 F.3d 1316, 1318-20 (11<sup>th</sup> Cir. 1998)(joining Third, Sixth, and Seventh Circuits in analogous interpretation of 21 U.S.C. § 841, regarding distribution of controlled substances).

In United States v. Chodor, 479 F.2d 661 (1<sup>st</sup> Cir. 1973), the First Circuit held that an exception set forth in a separate proviso within the operative definition of the crime of counterfeiting securities in 18 U.S.C. § 474 was an affirmative defense. The Court concluded that the Government was not required to offer evidence on the issue of whether the defendant was in possession of obligations "under authority from the Secretary of the Treasury or other proper official" where the statute provided in pertinent part:

Whoever has in his possession or custody, *except under authority from the Secretary of the Treasury or other proper office*, any obligation or other security made or executed, in whole or in part, after the similitude of any obligation or other security issued under the authority of the United States, with intent to sell or otherwise use the same . . .

18 U.S.C. § 474 (emphasis added). The First Circuit reasoned that the exception in the statute was an affirmative defense which the defendant was required to set up and establish. Id. at 663; accord, United States v. Green, 962 F.2d 938, 941 (9<sup>th</sup> Cir. 1992)(following "[t]he well-established rule . . . that a defendant who relies upon an exception to a statute made by a proviso or distinct clause, whether in the same section of the statute or elsewhere, has the burden of



establishing and showing that he comes within the exception.”). The Government has neither the obligation to allege an exception in the indictment nor the burden of going forward on the issue. United States v. Hester, 719 F.2d 1041, 1043 (9<sup>th</sup> Cir. 1983).

The discount exception in the Medicare Anti-Kickback Act is set forth in a separate subsection containing five different exemptions to the illegal remuneration defined in 42 U.S.C. § 1320a-7b(b)(1) and (2). The plain language of subparagraph (b)(3) of the Medicare Anti-Kickback Act is written as an exception to the crime of illegal remunerations stating “[p]aragraphs (1) and (2) shall not apply to—.” This language is nearly identical to the phrasing of the statute prohibiting possession and transfer of a machine gun, 18 U.S.C. § 922(o), “[t]his subsection does not apply with respect to—,” which both the Fifth and Eighth Circuits held to be an affirmative defense to be set up and proved by the defendant at trial, not an element of the offense that must be charged in the indictment. United States v. Just, 74 F.3d 902, 904 (8<sup>th</sup> Cir. 1995); United States v. Gonzales, 121 F.3d 928, 936-37 (5<sup>th</sup> Cir. 1997). Moreover, the term “remuneration” in the Medicare Anti-Kickback Act is broadly defined to include “any” remuneration. The narrowly drawn discount exception, like the other enumerated statutory exceptions, identifies a specifically defined payment practice.

Thus, the issue of whether or not the overt acts involving the marketing of return to practice to obtain and keep Lupron business falls within the statutory discount exception is an affirmative defense that the defendants had the burden to prove at trial.

### **III. The Defendants Have Not Met the Burden of Proving the Affirmative Defense.**

It was overwhelmingly proved at trial that TAP and these co-conspirators marketed RTP, encouraging physicians to charge AWP and not their discounted cost, inducing physicians to buy

Lupron by promising that the physician could pocket more money by buying Lupron than buying Zoladex. McAlpine testified that the "financial sell" was introduced in 1993, and various witnesses testified about being taught how to market RTP to doctors. In the Big Mac Attack in 1997, TAP referred to RTP as its "checkbook" and, as the evidence showed, those checks were drawn on the Medicare program. Thus, TAP and these conspirators actively sought to prevent the Medicare program from obtaining the benefit of the discounted prices on Lupron that they provided to physicians. Thus, these defendants did not establish any evidence, and can not claim, the benefit of the affirmative defense provided in the statutory discount exception to the Medicare Anti-Kickback Act because the discount was not "appropriately reflected" in the charges to the Medicare program. The purpose of the statutory discount exception was to ensure the Medicare program benefited from discounts to providers. The conduct of these co-conspirators was expressly designed to *prevent* Medicare from obtaining the benefit of those discounts, ensuring ever increasing profits to the doctor for buying Lupron over the cheaper and equally effective alternative GNRHa agonist.

**IV. The Defendants Have Not Met the Requirements of the Regulatory Discount Safe Harbor.**

Pursuant to enabling legislation in 1987, the Secretary of Health and Human Services clarified the discount exception in 1991 and again in 1999, promulgating the regulatory discount safe harbor discussed below. In enacting enabling legislation for the safe harbors, Congress charged HHS to clarify which, if any, payment practices should be protected, through a process that included a "determination of the scope of the statute and decisions as to how to draft the safe harbor provisions so that they protect only non-abusive relationships."

The discount safe harbor expressly provides that where a seller (such as TAP) provides a

discount to a buyer (such as a physician customer who submits his own reimbursement claims to Medicare), the seller must

fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

42 C.F.R. § 1001.952(h)(2)(iii)(B). In this trial, the evidence showed that physicians who did not buy sufficient quantities of Lupron to have a contract with TAP did not receive "notice" of their "obligations to report such discount" until July 1998 when the information was finally added to TAP's invoices. (e.g. 310.18 - Dr. Hwong's invoices). For Phoenix Urology, the language regarding a disclosure obligation, which Liz Dunst explained was necessary in the summer of 1996, was not added until the 1997 contract. Moreover, the evidence showed that TAP took deliberate steps to "impede" the buyer from meeting its obligations by (1) actively telling doctors to hide their actual prices in the Big Mac Attack, and by (2) providing "account reviews" or "reimbursement audits" that directed physicians to bill the AWP, rather than reporting a discount, which duty derives from the Medicare Anti-Kickback Act.

**V. If the Court Finds Some Evidence Presented by Defendants of Meeting the Regulatory Safe Harbor, the Issue Should be For the Jury to Decide.**

If the Court believes that some evidence has been presented on this affirmative defense, then the issue should be for the jury. The Government believes that no discount safe harbor instruction is warranted because the discounts were not "appropriately reflected" or "disclosed" given the way RTP was marketed by TAP. However, if some instruction is given, the government believes that the jury should be informed that the safe harbor can only be considered



after they find evidence that notice was affirmatively provided to the doctors by TAP.

Respectfully submitted,

MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY  
DISTRICT OF MASSACHUSETTS

By:

\_\_\_\_\_/s/\_\_\_\_\_  
MICHAEL K. LOUCKS  
HEALTH CARE FRAUD CHIEF  
SUSAN G. WINKLER  
GEORGE W. VIEN  
ASSISTANT U.S. ATTORNEYS

Dated: June 24, 2004

Certificate of Service

I hereby certify that this pleading has been served by e-mail.

\_\_\_\_\_/s/\_\_\_\_\_  
Susan G. Winkler